UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Wayne W. Marshall,

Plaintiff,

v.

Smith & Nephew, Inc.,

Defendant.

Civil No. 19-2313 (DWF/DTS)

MEMORANDUM OPINION AND ORDER

Debra Humphrey, Esq., Margaret Cordner, Esq., Stephen Monroe, Esq., Marc J. Bern & Partners LLP, and Earl Singh, Esq., Singh Advisors LLC, counsel for Plaintiff.

Pharaoh Johan Lewis, Esq., and Tracy J. Van Steenburgh, Esq., Nilan Johnson Lewis PA, counsel for Defendant.

INTRODUCTION

This matter is before the Court on a Motion to Dismiss brought by Defendant Smith & Nephew, Inc. ("Smith & Nephew"). (Doc. No. 6.) In his Complaint, Plaintiff Wayne W. Marshall ("Marshall") asserts a cause of action against Smith & Nephew for seven counts alleging negligence, strict products liability, breach of express warranty, breach of implied warranty, negligent misrepresentation, and unjust enrichment. (Doc. No. 1-1 "Compl.").) For the reasons set forth below, the Court grants Defendant's motion, dismissing Marshall's complaint with prejudice in part and without prejudice in part.

BACKGROUND

Plaintiff Marshall is a Minnesota resident, while Defendant Smith & Nephew is a Delaware corporation with a principal place of business in Tennessee. (Compl. ¶¶ 7-8.)

Marshall alleges seven counts against Smith & Nephew related to Marshall's knee replacement surgery performed by Dr. Michael Wengler ("Dr. Wengler") on July 2, 2012. (Compl. ¶ 14.) Marshall underwent a unicondylar knee arthroplasty procedure to treat medial osteoarthritis in his right knee using a Smith & Nephew Journey Knee System consisting of a right tibial baseplate size 5 component, a femur size 5 component, and an 8mm spacer component (the "Product"). (*Id.* ¶¶ 15-16.) Sometime after this procedure, Marshall experienced "severe pain and discomfort" in his right knee. (*Id.* ¶ 17.) Upon the recommendation of his treating medical professionals, due to the loosening of hardware in the Product, on August 3, 2017 Marshall underwent revision surgery to remove and replace the Product. (*Id.* ¶¶ 18-19.) Since this revision surgery, Marshall continues to experience "severe pain and discomfort" in his right knee. (*Id.* ¶ 20.)

Marshall contends as to Count I that Smith & Nephew designed, manufactured, distributed, and placed the Product into the stream of commerce and was solely responsible for its design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and distribution during the relevant time period. (*Id.* ¶¶ 21-22.) Marshall further alleges that Smith & Nephew had in its possession information about the rate of loosening and failure of the Product during the same period, and that Smith & Nephew failed in its duty to exercise reasonable care and to take all reasonable steps necessary to

manufacture and sell a product that was not defective and unreasonably dangerous to users. (*Id.* ¶¶ 24, 26.) Marshall also alleges that Smith & Nephew knew, or should have known, that the Product would loosen and fail as a result of this failure to exercise reasonable care, causing injury to consumers such as Marshall, and that Marshall did in fact sustain serious personal injuries and losses including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for enjoyment of life, diminished quality of life, and medical and related expenses. (*Id.* ¶¶ 27-29.) Marshall also states in his Complaint that he "intends to move to amend his Complaint to assert a claim for punitive damages." (*Id.* ¶ 29.)

In Counts II and III, Marshall alleges strict products liability for design defect and failure to warn without specifics, alleging that the Product was unreasonably dangerous because it was "designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed and sold in a defective condition" by Smith & Nephew for consumer use. (*Id.* ¶¶ 31-33.) Marshall contends that Smith & Nephew knew or should have known that the defective state of the Product held a foreseeable risk to users exceeding the Product's claimed benefits when used as its was manufactured and distributed in the manner intended. (*Id.* ¶¶ 35-36.) Marshall alleges that his healthcare providers used the Product for its intended purpose in treating Marshall, causing injury and loss. (*Id.* ¶¶ 37-38.) Marshall additionally alleges that Smith & Nephew failed to provide adequate warning to warn ordinary users of substantial danger presented by use of the Product in the manner intended or in a

reasonably foreseeable manner, resulting in injuries and losses suffered by Marshall. (*Id.* ¶¶ 42-45.)

Again without detail, Marshall alleges that Smith & Nephew breached both an express and an implied warranty in Counts IV and V, stating that Smith & Nephew "expressly warranted" that the Product was safe, effective, fit for use by consumers, of merchantable quality, did not create risk of dangerous side effects, and was adequately tested and fit for its intended use, when in fact Smith & Nephew "had full knowledge" that the Product did not conform to these warranties and representations and carried a risk of "severe pain and surgery," such as the harm Marshall suffered. (*Id.* ¶¶ 47-49.) Marshall contends that healthcare professionals, including Marshall's treating physicians, relied upon Smith & Nephew's express warranties in buying and using the Product. (*Id.* ¶¶ 51-53.) According to Marshall, Smith & Nephew also made false and misleading implied representations and warranties of the Product's safety and quality to "the medical community," regulatory agencies, and consumers including Marshall and his physicians by marketing and selling the Product for use in knee replacement, knowing that it was not fit for this intended use and purpose. (*Id.* ¶¶ 55-62.)

Marshall alleges that Smith & Nephew also negligently misrepresented the Product to users, including Marshall and "members of the general public," as safe and effective when Smith & Nephew knew, or should have known, that use of the Product carried an "increased risk of severe pain and surgery." (*Id.* ¶¶ 66-68, 72-73.) He contends that Smith & Nephew knew, or had reason to know, that the Product had not been "sufficiently tested" and that its use created a "high risk of adverse health effects"

and "higher than acceptable risks of harm. (*Id.* ¶ 76.) Marshall alleges that he and his treating physicians were among the members of the general public who "justifiably relied" on misrepresentations made by Smith & Nephew, resulting in Marshall's injuries and losses. (*Id.* ¶¶ 73-75.)

Finally, Marshall alleges that in accepting payment for the Product, Smith & Nephew was unjustly enriched because Marshall did not receive a safe and effective knee replacement. (*Id.* ¶¶ 80-83.) Marshall seeks money damages in excess of $50,000 as well as lost wages, treble damages pursuant to Minnesota law, disgorgement of profits, restitution of costs, attorneys' fees, pre- and post-judgment interest, delay damages, and such other relief the Court finds just and proper. (*Id.* at 18.)

Defendant Smith & Nephew removed the case to federal court on August 21, 2019, invoking diversity jurisdiction. (Doc. No. 1.) Smith & Nephew now moves to dismiss Marshall's claims under Federal Rule of Civil Procedure 12(b)(6). (Doc. No. 6.) Smith & Nephew argues that Marshall fails to allege sufficient facts to state a claim upon which relief may be granted, fails to plead with the specificity required under Rule 8(a), and with respect to his negligent misrepresentation claim, fails to meet the heightened standard for pleading a fraud claim under Rule 9(b). (Doc. No. 8 ("Def. Mem.") at 1.) According to Smith & Nephew, Marshall fails to allege facts sufficient to meet the pleading standards for his claims because "his allegations are essentially conclusory statements unsupported by any facts." (Def. Mem. at 4-5.) Specifically, Smith & Nephew contend that the Complaint is missing facts to show that the Product was defective when it left Smith & Nephew's control, or to identify the defective

condition of the Product that made it unreasonably dangerous for its intended use, or to establish that the defective condition caused loosening and failure of the Product. (*Id.* at 5-6.) Smith & Nephew also contend that the Complaint lacks facts with respect to the issue of balancing the likelihood and gravity of possible harm against the burden of effective precautions against it. (*Id.* at 6.)

As to the issue of insufficient warnings issued by the defendant, Smith & Nephew points out that Marshall does not allege whether actual or constructive knowledge of substantial danger existed, whether a warning was given, and if so, to whom and how it was inadequate. (*Id.* at 7-8.) Smith & Nephew goes on to argue that Marshall's warranty claims are time-barred under Minnesota law, and in any event, they are also insufficiently pled. (*Id.* at 8-9.) Smith & Nephew further notes that under Minnesota law, allegations of misrepresentation are considered allegations of fraud which must be pled with particularity, and argue that Marshall fails to support a claim of negligent misrepresentation under Rule 9(b) because his Complaint does not identify the content of the misrepresentations alleged or the circumstances under which they were made. (*Id.* at 11-12.) Lastly, Smith & Nephew states that Marshall's claim with respect to unjust enrichment is deficient as it does not "identify why Smith & Nephew is not entitled to payment for the Product, in what way the Product was not safe and effective or why he is entitled to a return of the sum he paid for the Product." (*Id.* at 13.)

Marshall concedes that his claims for breach of express and implied warranties were not timely and should be dismissed. (Doc. No. 27 at 10.) However, Marshall maintains that his Complaint is otherwise sufficient, and that not only is he not required

at this stage in proceedings to plead every claim with the same specificity as for fraud, he is not permitted to do so under Rule 8(a)(2). (*Id.* at 9.) Read as a whole, Marshall contends, the Complaint gives Smith & Nephew adequate notice of his claims. (*Id.*) Should the Court find differently as to his claim of negligent misrepresentation, Marshall requests that it be dismissed without prejudice so that he may amend his complaint.[1] (*Id.* at 14.)

DISCUSSION

I. Legal Standards

A. Motion to dismiss

In deciding a motion to dismiss pursuant to Rule 12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged, *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6). *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

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[1] Marshall did not formally move for leave to amend his complaint in the months between the filing of Smith & Nephew's Motion to Dismiss and the hearing on the matter. (*See* Doc. Nos. 6, 44.)

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). Fed. R. Civ. P. 8(a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. As the United States Supreme Court reiterated, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

B. Applying state law

The parties are of diverse citizenship and Marshall seeks damages and alleges injuries that likely establish an amount in controversy above the $75,000 threshold required for diversity jurisdiction. Marshall tacitly conceded that this case is properly in federal court on the basis of diversity jurisdiction. (Doc. No. 43 (Plaintiff's letter withdrawing his motion to remand).) As this is a diversity action, the Court applies federal procedural law and state substantive law, interpreting Minnesota law in determining whether the elements of the claims have been pled.[2] *See Erie R.R. v.*

[2] Marshall's Complaint is dated July 31, 2019 and Smith & Nephew removed this action from state court on August 21, 2019. (Doc. No. 1; Compl.) Marshall moved to

(Footnote Continued on Next Page)

Tompkins, 304 U.S. 64, 78 (1938); *Ashley Cty., Ark. v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009).

II. Preemption

The deficiencies in Marshall's Complaint are numerous and the Complaint does not lend itself easily to an orderly analysis. In the interest of completeness, several potential issues are addressed here in order to explain the Court's reasoning. To start, the parties' submissions have largely ignored the fact that the Product is a medical device, often supporting their positions with caselaw that applies more broadly to product liability claims. Marshall has not furnished details about the exact model and generation of the Journey device used, preventing the Court (to the extent it is inclined to engage in supplemental research) from finding relevant public records describing the Product's status with the U.S. Food and Drug Administration ("FDA").[3] Exacerbating the challenges presented, Marshall alleges claims in broad terms without specifying any statute or act that Smith & Nephew violated, making it difficult to know what law or laws he invokes.

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remand but later withdrew his motion. (Doc. Nos. 18, 43.) At oral arguments held on November 8, 2019, counsel for Smith & Nephew asked the Court to consider sanctions against Marshall for withdrawing the motion in the same week the hearing was scheduled. (Doc. No. 44 ("Motion Hr'g").) The Court reserved the right to have the parties submit letter briefs on the issue and details its requirements in the Order below.

[3] At oral arguments, the Court asked Plaintiff's counsel if the Product was the same Smith & Nephew Journey Knee System about which the Court found publicly available information, but counsel was unable to confirm whether this was the case. (Motion Hr'g.) Counsel for Smith & Nephew were likewise unable to discern which generation device was used in Marshall's first surgery. (*Id.*) The Court notes that basic information about a specific medical device, such as its classification, 510(K) number, and applicable recalls can be found on the FDA's website at https://www.fda.gov.

The Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, may preempt some or all of Marshall's claims. "The general law of preemption is grounded in the Constitution's command that federal law 'shall be the supreme Law of the Land,'" meaning that state law that conflicts with federal law has no effect. *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 938 (8th Cir. 2011) (quoting *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781, 791 (8th Cir. 2010) (in turn quoting U.S. Const. art. VI, cl. 2)). Congressional purpose is the "ultimate touchstone" in a preemption case, because whether a certain federal law preempts a state law depends upon it. *Lefaivre*, 636 F.3d at 938. Congress "does not cavalierly pre-empt state-law cause of action," and the "historic police powers of the States" are not superseded unless it is the "clear and manifest purpose" of a federal act. *Id.* In passing the MDA, Congress did not apply its preemption clause to the entire FDCA, instead writing a preemption provision that only applies to medical devices. *Id.* at 940 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008)).

The MDA were enacted by Congress to provide for the safety and effectiveness of medical devices intended for human use. *Lamere v. St. Jude Med., Inc.*, 827 N.W.2d 782, 789 (Minn. Ct. App. 2013) (citing *Medtronic v. Lohr*, 518 U.S. 470, 474 (1996).) Medical devices are categorized by the risk of injury or illness they pose to the public, with Class III devices subject to the highest level of FDA scrutiny. *See* 21 U.S.C. § 360c(a)(1); *Riegel*, 552 U.S. at 317; *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

The MDA preemption clause states:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

Before a Class III device can be marketed, it must complete a "rigorous" process to obtain pre-market approval ("PMA") during which the device maker must provide the FDA "reasonable assurance" that the device is safe and effective. *In re Medtronic*, 592 F. Supp. 2d at 1150 (citing 21 U.S.C. § 360e(d)(2)). Once a device receives PMA, its maker may not change the design specifications, manufacturing processes, labeling, or any other attribute that would affect the device's safety or efficacy without approval from the FDA, and the manufacturer must inform the FDA when it becomes aware of adverse events in patients using the device. *Id.* at 1150. Class III devices can also enter the market through an FDA review for substantial equivalence known as the § 510(k) process, which focuses on equivalence, not safety. *Riegel*, 552 U.S. at 317, 323.

In its *Riegel* opinion, the Supreme Court held that for the purposes of the MDA preemption provision, PMA is a federal safety review that results in "federal requirements" specific to the approved device, and common law product liability claims result in "state requirements" that are preempted to the extent they relate to the safety and effectiveness of the device and are different from, or in addition to, the federal requirements established by PMA. *In re Medtronic Inc., Sprint Fidelis Leads Prod. Liab.*

Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (citing *Riegel* at 322-24). A State may, however, provide a damages remedy for claims premised on a violation of FDA regulations—the state duties in such a case "parallel" federal requirements rather than adding requirements. *Id.*

Pursuant to the MDA, all actions to enforce FDA requirements "shall be by and in the name of the United States." *Id.* (citing 21 U.S.C. § 337(a)). The Supreme Court construed § 337(a) as barring suits by private citizens for noncompliance with the medical device provisions in its *Buckman* opinion. *Id.* (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001)). Reading *Buckman* together with *Riegel*, the Eighth Circuit has held that these opinions "create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Id.* The "critical question" is whether a claim is parallel—a suit must be for conduct that violates the FDCA to avoid express preemption under § 360k(a), but a plaintiff cannot bring a state law claim that is in form or substance for violating the FDCA or it is impliedly preempted under *Buckman*. *Id.* at 1204-05; *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776-77 (D. Minn. 2009).

Marshall's failure to provide details about the FDA categorization of the Product hinders the Court's ability to determine whether it had received PMA or completed the § 510(k) process at the time of Marshall's procedure, which in turn makes it impossible to fully evaluate whether his claims are preempted by the FDCA. For example, a claim for failure to warn is preempted where a product has received PMA because such approval includes requirements for specific language for device labels and warnings. *Id.*

at 1205. If by reason of Minnesota law Smith & Nephew was required to give additional warnings, this requirement would be "different from or in addition to" the federal requirement and therefore preempted. *Id.* (citing *Riegel* at 330; *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005). A state law claim for failure to warn might not be preempted, however, if it is based on a device maker's failure to warn the FDA of adverse events in violation of federal requirements under 21 U.S.C. § 360i(a) that parallel traditional Minnesota tort law. *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404, 419 (Minn. Ct. App. 2015).

As another example, Minnesota law requires plaintiffs asserting design defect claims to apply a reasonable-care balancing test and explain why "the world would be a better place if the product were either designed differently or taken off the market." *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1161 (D. Minn. 2011) (discussing Minnesota law). An attack on the risk/benefit analysis completed in the FDA's approval process would not be parallel; it would disrupt the federal scheme, and consequently it would be expressly preempted. *Id.* at 1206 (internal citations omitted); *see also Lamere*, 827 N.W.2d at 792 (finding that imposing the state's strict-liability rules on a PMA device would impose a general duty that would directly regulate the device itself and be a regulation different from the applicable federal regulations). However, a manufacturing defect claim pursuant to Minnesota law to the extent it parallels federal requirements for manufacturing practices may not be preempted. *Riley*, 625 F. Supp. 2d at 789. Similarly, a claim under state law for fraud on consumers, rather than on the FDA, may be sustained if sufficiently pled. *Lefaivre*, 636 F.3d at 944.

To determine whether Marshall's claims are preempted, the Court must first determine whether federal requirements have been established for the Product, and if so, then ask whether his state common-law claims are based upon Minnesota requirements that relate to safety and effectiveness and are "different from, or in addition to" the federal requirements. *Riegel*, 550 U.S. at 321-22 (citing § 360k(a)). Insofar as Marshall's claims are preempted, they must be dismissed. The Complaint does not specify the class designation of the Product or provide information about which approval process it completed before being placed on the market. Without these crucial details, the Court cannot engage in a meaningful analysis of each claim's plausibility and must dismiss them.

The Court notes that even if it was inclined to infer that the claims are not preempted based on the meager information before it, they must be dismissed as insufficiently pled under state law, as explained below.

III. Negligence

To state a claim for negligence under Minnesota law, Marshall must show the existence of a duty of care owed to him by Smith & Nephew, a breach of that duty, and an injury proximately caused by that breach. *Thunander v. Uponor, Inc.*, 887 F. Supp. 2d 850, 869 (D. Minn. 2012) (applying Minnesota law). The vagueness of the Complaint results in a variety of possible reasons this claim fails related to preemption and insufficient pleading. Without attempting to explain each reason, the Court finds that this claim fails because Marshall has failed generally to provide facts to show any breach of duty on Smith & Nephew's part or how this hypothetical breach might have caused him

injury. Marshall has not provided facts to show how his condition changed over the years-long period in question, and even assuming, as the Court must, that he was advised to undergo an additional procedure due to the loosening of some unspecified part of the Product, that fact alone does not show how the Product's performance constituted breach of a duty held by Smith & Nephew or how such a breach proximately caused Marshall harm. As a result, Count I is dismissed, with prejudice to the extent that it is preempted, and without prejudice as to any remaining state law claim.

IV. Strict products liability

A. Design defect

Strict liability and negligence theories are merged under Minnesota law into a single products liability theory. *Thompson v. Hirano Tecseed Co.*, 456 F.3d 805, 809 (8th Cir. 2006) The distinction between strict liability and negligence in design-defect and failure-to-warn cases is that in the former, knowledge of the condition of the product and the risks involved in that condition will be imputed to the manufacturer, while in the latter, these elements must be proven. *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 622 (Minn. 1984).

To establish a design defect, Marshall must present facts to show that (1) the Product was in a defective condition unreasonably dangerous for its intended use, (2) the defect existed when it left Smith & Nephew's control, and (3) the defect proximately caused his injury. *Thompson*, 456 F.3d at 809. Whether a product is defective is determined by applying a reasonable-care balancing test, weighing the likelihood of harm and the gravity of harm if it happens against the burden of an effective precaution against

the harm. *Id.* (citing *Westbrock v. Marshalltown Mfg. Co.*, 473 N.W.2d 352, 356 (Minn. Ct. App. 1991); *Bilotta*, 346 N.W.2d at 623 n.3.) To establish a manufacturing defect claim, the defect is determined by focusing on the condition of the product as compared against a "flawless" product. *Bilotta* at 622.

It is true that Minnesota law allows a plaintiff to use the doctrine of *res ipsa loquitur* to prove a product liability claim based upon negligence and strict liability (*Holkestad v. Coca-Cola Bottling Co.*, 180 N.W.2d 860, 865-66 (Minn. 1970)), but application of the doctrine is limited to cases where the cause of injury is "reasonably certain" (*Raines v. Sony Corp. of Am.*, 523 N.W.2d 495, 497 (Minn. Ct. App. 1994)).

Marshall's allegations are too vague to effectively allege violations of parallel federal and state requirements that resulted in defects in the Product. For the reasons outlined above, this claim is almost certainly preempted by the FDCA. Even under Minnesota law, however, it is insufficiently pled. Marshall does not allege facts showing that the Product was unreasonably dangerous, falling far short of showing that Smith & Nephew knew or should have known that the Product would be unreasonably dangerous for the use for which it was supplied. Further, without any detail on his condition, the outcome anticipated, or other potential factors leading to his symptoms and revision surgery, Marshall has not offered any facts to support an inference that the Product caused him injury. Consequently, Count II is dismissed, with prejudice to the extent that it is preempted by the FDCA, and without prejudice as to any remaining state law claim that is not expressly or impliedly preempted.

B. Failure to warn

To establish a negligent failure to warn claim under Minnesota law, Marshall must show that Smith & Nephew had reason to know the danger of using the Product, breached its duty of care by providing inadequate warnings, and that the lack of adequate warning caused injury to Marshall. *Thunander*, 887 F. Supp. 2d at 869 (internal citations to Minnesota caselaw omitted). A manufacturer has a duty to warn users of its products of all dangers associated with those products of which it has actual or constructive knowledge. *Mozes v. Medtronic*, 14 F. Supp. 2d 1124, 1129 (D. Minn. 1998) (citing Minnesota caselaw). This duty to warn is narrow, requiring only that it give adequate instructions for safe use and warn of dangers inherent in improper use. *Kapps*, 813 F. Supp. 2d at 1152 (citing *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 787 (Minn. 1977)).

Minnesota recognizes the learned intermediary doctrine, under which a maker of drugs or medical devices only has a duty to warn doctors, and not patients, about the dangers associated with its product. *Kapps* at 1152 (internal citations and quotations omitted). A patient's failure-to-warn claim is foreclosed if his or her doctor received adequate warning from the manufacturer of the medical device in question. *Id.* Such a claim is also foreclosed if the doctor was aware of the information the manufacturer failed to provide or would have taken the same action even if warned. *Id.*

Here, Marshall has failed to offer facts showing that the Product was dangerous, Smith & Nephew's knowledge of any risk, what warnings were or should have been issued (by and to whom), or how such a hypothetical warning would have changed the

course of events. Accordingly, Count III is dismissed with prejudice to the extent it is preempted and without prejudice to the extent Marshall can replead a viable claim.

V. Breach of warranty

As noted above, Marshall withdrew his claims for breach of both express and implied warranties so they do not require further discussion. (*See* Doc. No. 27 at 10.) Counts IV and V are dismissed with prejudice.

VI. Negligent misrepresentation

The Federal Rules of Procedure govern diversity cases when there is no conflict with state procedures. *Roberts v. Francis*, 128 F. 3d 647, 650 (8th Cir. 1997). Rule 9.02 of the Minnesota Rules of Civil Procedure does not conflict with Fed. R. Civ. P. 9(b) in its requirement that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Accordingly, Marshall must meet the heightened pleading requirements of Fed. R. Civ. P. 9(b). *Tharaldson v. Ocwen Loan Servicing, LLC*, 840 F. Supp. 2d 1156, 1164 (D. Minn. 2011). Rule 9(b) of the Rules of Civil Procedure requires that in alleging fraud or mistake, "a party must state with particularity the circumstances constituting fraud or mistake." The complaint must include allegations of matters such as "the time, place, and contents of false representations, as well as the identity of the person making the representation and what was obtained or given up thereby," and conclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient. *Schaller Tel. Co. v. Golden Sky Sys., Inc.*, 298 F.3d 736, 746 (8th Cir. 2002) (internal quotations and citations omitted). Allegations of fraud may be pleaded on information and belief when the facts

constituting the fraud "are peculiarly within the opposing party's knowledge." *Drobnak v. Andersen Corp.*, 561 F.3d 778, 783-84 (8th Cir. 2009).

Under Minnesota law, allegations of misrepresentation, whether labeled as fraudulent or negligent, are considered allegations of fraud. *Trooien v. Mansour*, 608 F.3d 1020, 1028 (8th Cir. 2010). The elements of a fraud claim under Minnesota law are: (1) a false representation by a party of a past or existing material fact susceptible of knowledge; (2) made with knowledge of the falsity of the representation or made as of the party's own knowledge without knowing whether it was true or false; (3) with the intention to induce another to act in reliance thereon; and (4) that the party suffer pecuniary damage as a result of the reliance. *Angeles*, 863 N.W.2d at 422 (citing *Specialized Tours, Inc. v. Hagen*, 392 N.W.2d 520, 532 (Minn. 1986)). Negligent misrepresentation differs only in what a plaintiff must show about the defendant's state of mind, requiring that the defendant supplied false information for the guidance of others in its business transactions and in doing so failed to exercise reasonable care or competence in obtaining or communicating the information. *Trooien*, 608 F.3d at 1028 (citing *Florenzano v. Olson*, 387 N.W.2d 168, 174 n. 3 (Minn. 1986)).

Marshall has not identified statements made by or on behalf of Smith & Nephew that were allegedly false or misleading and that were relied upon by either himself or his doctors. Without facts to show that he or his treating physicians were misled, Marshall's claim for fraud is insufficient, and is therefore dismissed with prejudice to the extent that it is preempted and without prejudice to the extent that he can replead a plausible claim for relief.

VII. Unjust enrichment

To make a claim for unjust enrichment, Marshall must show that Smith & Nephew knowingly received or obtained something of value for which it should pay "in equity and good conscience." *Klass v. Twin City Fed. Sav. & Loan*, 190 N.W.2d 493, 495 (Minn. 1971). To show that the defendant was "unjustly enriched," Marshall must show enrichment that was unjust in the sense that it was illegal or unlawful. *First Nat'l Bank v. Ramier*, 311 N.W.2d 502, 504 (Minn. 1981). Although a claim for equitable relief is only available when no adequate legal remedy exists, a plaintiff may plead alternative theories of relief even if they are inconsistent. *Drobnak*, 561 F.3d at 787; Fed. R. Civ. P. 8(d)(2),(3). This claim is not foreclosed by Marshall's competing claims, but for the reasons discussed above, the Court is unable to discern from Marshall's pleading any way that Smith & Nephew acted illegally or unlawfully, even assuming that all facts asserted are true and construing all reasonable inferences in Marshall's favor. As a result, this claim is dismissed without prejudice.

CONCLUSION

A pleading that is sufficient under Rule 8(a)(2) must be "short and plain" but it must also show that the pleader is entitled to relief. A pleading offering "labels and conclusions," "a formulaic recitation of the elements of a cause of action," or "naked assertions devoid of further factual enhancement" is insufficient. *Horras v. Am. Capital Strategies, Ltd.*, 729 F.3d 798, 801 (8th Cir. 2013) (quoting *Iqbal* at 678, in turn quoting *Twombly* at 555, 557). As noted above, this Court is not required to accept Plaintiff's legal conclusions. *Westcott*, 901 F.2d at 1488. Marshall has not presented facts to

support his assertions that are sufficient to withstand dismissal, even assuming that all facts asserted are true and construing all reasonable inferences in his favor.

Marshall provides facts to show that he experienced severe pain and related injuries before his surgery, after his first surgery, and since his revision surgery to replace the Product. There is nothing in the record to establish precisely which device was used in Marshall's first procedure, much less the expected service life of the Product and any personal aspects of Marshall's condition that might factor into his and his treating physicians' reasonable expectations for the Product's performance, nor has Marshall pled any facts about the existence of communications between the parties or their possible content. With such scant information, the Court's analysis has been frustrated to such a degree that it is skeptical that Marshall will be able to present a set of facts warranting relief. The Court further observes that Smith & Nephew pointed out at least some of the deficiencies in Marshall's Complaint months before oral arguments were held in this matter, yet Marshall did not request leave to amend or indicate what changes he would make given the chance. However, it does seem that it is possible that—with supporting evidence, perhaps gained through limited discovery—Marshall will sufficiently state a claim. Because of this possibility, and despite circumstances that would justify an exercise of the Court's discretion to deny leave to amend, the Court is reluctant to dismiss all of Marshall's claims with prejudice and grants Marshall leave to amend with respect to some of his claims.

ORDER

Based upon the foregoing, and on all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendant Smith & Nephew's Motion to Dismiss Plaintiff's Complaint (Doc. No. [6]) is **GRANTED** as follows:

   a. Counts I through III and Counts VI and VII, to the extent that they are not preempted by federal law, are **DISMISSED WITHOUT PREJUDICE.**

   b. Count IV for breach of express warranty and Count V for breach of implied warranty are **DISMISSED WITH PREJUDICE.**

2. Plaintiff Wayne W. Marshall may file an amended complaint asserting the claims **dismissed without prejudice** no later than thirty days from the date of this Order. Failure to file within thirty days will result in a final judgment of dismissal on all counts.

3. The Court will consider a written motion for sanctions regarding Plaintiff's withdrawn motion for remand (Doc. No. 18). Defendant Smith & Nephew may submit a letter brief up to five pages in support of such a motion no later than 15 days from the date of this order. Plaintiff Marshall may submit a letter brief up to five pages in response no later than 15 days from the filing of Defendant's brief, or 30 days from the date of this Order, whichever is earlier.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: January 22, 2020

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge